

**REMARKS/ARGUMENTS**

Reconsideration is requested. Claims 1-15 are pending. Responsive to the Office Action of October 26, 2005, the Examiner's comments and the cited art have been noted and studied. For reasons to be set forth in detail below, it is respectfully submitted that the present application is in condition for allowance, and such action is requested.

Independent claim 1 has been amended to clearly recite that the signal-producing systems of the first, second and third test strips are signal-producing "reagent" systems that produce signals indicative of organ marker, drug, and metabolite concentrations, respectively. See, for example, page 20, lines 3-11, page 21, lines 12-27 and page 22, lines 17-29 of the original disclosure.

In addition, independent claim 1 has been amended to recite that the single integrated test device has means for determining organ marker, drug and metabolite concentrations from the respective produced signals (see, for example, page 21, lines 18-20 and page 22, lines 22-25 of the original disclosure). Moreover, claim 1 has been amended to recite that the display step occurs on a display of the single integrated test device (see, for example, page 21, lines 21-22 of the original disclosure).

Independent claim 1 has also been amended for clarity and consistency of terminology.

It is respectfully submitted that the amendments above are supported by the specification, claims, abstract of the disclosure, and drawings as originally filed, and that no new matter has been added.

**Rejections under 35 U.S.C. §102 and §103:**

The subject matter of claims 1-10 and 13-14 was rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,469,035 to Cefali (hereinafter "Cefali"). The subject matter of claims 11, 12 and 15 was rejected under 35 U.S.C. §103(a) as obvious over Cefali.

Cefali, as understood, describes methods for altering serum lipid levels in individuals (see, for example, col. 6, lines 39-44 of Cefali. The methods of Cefali are characterized by, for example, the tabulation of lipid profiles and liver enzyme levels (see, for example, Tables

I, II and III of Cefali). Cefali does not seem to teach, describe or suggest the methods and associated devices that were used to obtain the lipid profiles or liver enzyme levels.

Independent claim 1, as amended, recites a specific method for determining and displaying organ marker, drug and/or metabolite concentrations using test strips and a single integrated test device. Such a method and its benefits (e.g., simplicity and timeliness) are simply not taught, described or suggested by Cefali.

For at least the foregoing reasons, Applicants submit that independent claim 1, as amended, is neither anticipated nor obvious over Cefali. Since dependent claims 2-15 directly or indirectly depend from and further limit independent claim 1, they are allowable for at least the same reasons.

### CONCLUSION

Applicants respectfully request that, in light of the amendments and explanations above, the Examiner reconsider and withdraw the rejections. Applicants respectfully submit that the claims are in condition for allowance. In the event that minor claim amendments are necessary to meet formal requirements, Applicants invite the Examiner to telephone the undersigned at (408) 956-4790 so that issuance can be expedited.

If the Examiner deems a telephone interview is necessary, he is invited to telephone the undersigned attorney of record at (408) 956-4790. The Commissioner is hereby authorized to deduct any deficiencies, or to credit any overpayment, to Deposit Account No. 10-0750 (DDI0038USDIV/MM).

Respectfully submitted,

/Mayumi Maeda/

By: \_\_\_\_\_  
Mayumi Maeda  
Reg. No. 40,075

Serial No. 10/623,019

Johnson & Johnson  
International Patent Law Division  
Attention Philip Johnson  
P.O. Box 1222  
New Brunswick, NJ 08903  
(408) 956-4790  
Dated: April 17, 2006